

NHS England and NHS Improvement: Equality and Health Inequalities Impact Assessment (EHIA)

1. Name of the proposal (policy, proposition, programme, proposal or initiative)¹:

Clinical Commissioning Policy: Vismodegib for adults with either Gorlin syndrome or non-Gorlin syndrome related multiple basal cell carcinomas [NHS England and NHS Improvement URN: 1905]

2. Brief summary of the proposition in a few sentences

Basal cell carcinoma (BCC) is a non-melanoma type skin cancer and is the most common type of skin cancer in the UK, accounting for 80% of total skin cancer cases. People with multiple BCC develop lesions frequently and at different sites in the body. The most common treatment for multiple BCC is surgery, however, these procedures can be potentially disfiguring and have an impact on the patient's quality of life.

The policy recommends that vismodegib, a targeted cancer treatment, be made available for the treatment of adults with:

- Gorlin syndrome (also known as basal cell nevus syndrome): This is an inherited genetic disorder in which people develop basal cell carcinomas from an early age (teens or 20s), as well as other abnormalities such as cysts in the jaw bone and ovarian tumours. They may develop hundreds of basal cell carcinomas over a lifetime, OR;
- Non-Gorlin related multiple basal cell carcinomas; these are frequently elderly people who have worked outside or who have spent long periods in sunny areas of the world (e.g. the armed forces).

Vismodegib would be an alternative treatment to surgery for adults with either Gorlin syndrome or non-Gorlin syndrome related multiple BCC who have a minimum of 6 lesions where surgery could result in significant disfiguration. The policy has been restricted to adults because the drug the Marketing Authorisation does not recommend its use in children and adolescents aged below 18 years due to safety concerns in this population.

¹ Proposal: We use the term proposal in the remainder of this template to cover the terms initiative, policy, proposition, proposal or programme.



The policy has been developed in line with the findings of an evidence review and in accordance with NHS England's standard Methods for clinical commissioning policies.

3. Main potential positive or adverse impact of the proposition for protected characteristic groups summarised

Please briefly summarise the main potential impact (positive or negative) on people with the nine protected characteristics (as listed below). Please state **N/A** if your proposition will not impact adversely or positively on the protected characteristic groups listed below. Please note that these groups may also experience health inequalities.

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposition	Main recommendation from your proposition to reduce any key identified adverse impact or to increase the identified positive impact
<p>Age: older people; middle years; early years; children and young people.</p>	<p>Non-melanoma skin cancer, such as BCC, is strongly related to age with the highest incidence rates being in older people. In the UK in 2015-2017, on average each year almost half (47%) of new cases were in people aged 75 and over (Cancer Research UK, 2020a).</p> <p>However, cancers occurring in people with Gorlin syndrome usually occur in younger people with BCCs developing around the age of 30 (Cancer Research UK, 2020b).</p> <p>A review of the available clinical evidence demonstrates that use of vismodegib resulted in a reduction in the size and number of BCCs, thereby reducing the need for surgery which could in some cases be potentially disfiguring. For this</p>	<p>The clinical criteria, based on reliable clinical evidence, in the policy clearly define the eligible patient population to maximise access to treatment.</p> <p>Treatment numbers and access would be monitored through NHS England and NHS Improvement's Prior Approval System.</p>

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposition	Main recommendation from your proposition to reduce any key identified adverse impact or to increase the identified positive impact
	reason, implementation of the policy is considered to have a potential positive impact on older people and people in their middle years.	
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	Being diagnosed with cancer is defined as a disability under the Equality Act 2010. A review of the available clinical evidence demonstrates that use of vismodegib resulted in a reduction in the size and number of BCCs, thereby reducing the need for surgery which could in some cases be potentially disfiguring. For this reason, implementation of the policy is considered to have a potential positive impact.	The clinical criteria, based on reliable clinical evidence, in the policy clearly define the eligible patient population to maximise access to treatment. Treatment numbers and access would be monitored through NHS England and NHS Improvement's Prior Approval System.
Gender Reassignment and/or people who identify as Transgender	Not applicable.	Not applicable.
Marriage & Civil Partnership: people married or in a civil partnership.	Not applicable.	Not applicable.
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	Not applicable.	Not applicable.

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposition	Main recommendation from your proposition to reduce any key identified adverse impact or to increase the identified positive impact
Race and ethnicity ²	<p>Skin type is considered to be a risk factor for non-melanoma skin cancers, with fairer people more likely to suffer from the disease. Research indicates that Basal cell carcinoma (BCC) risk is 70% higher in people with skin phototype I/II (i.e. people with freckles, red or fair hair, and blue or green eyes; or people with light hair and blue and brown eyes), compared with people with skin phototype III/IV (brown hair and brown eyes) (Cancer Research UK, 2018).</p> <p>A review of the available clinical evidence demonstrates that use of vismodegib resulted in a reduction in the size and number of BCCs, thereby reducing the need for surgery which could in some cases be potentially disfiguring. For this reason, implementation of the policy is considered to have a potential positive impact.</p>	<p>The clinical criteria, based on reliable clinical evidence, in the policy clearly define the eligible patient population to maximise access to treatment.</p> <p>Treatment numbers and access would be monitored through NHS England and NHS Improvement's Prior Approval System.</p>

² Addressing racial inequalities is about identifying any ethnic group that experiences inequalities. Race and ethnicity include people from any ethnic group incl. BME communities, non-English speakers, Gypsies, Roma and Travelers, migrants etc.. who experience inequalities so includes addressing the needs of BME communities but is not limited to addressing their needs, it is equally important to recognise the needs of White groups that experience inequalities. The Equality Act 2010 also prohibits discrimination on the basis of nationality and ethnic or national origins, issues related to national origin and nationality.

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposition	Main recommendation from your proposition to reduce any key identified adverse impact or to increase the identified positive impact
Religion and belief: people with different religions/faiths or beliefs, or none.	Not applicable.	Not applicable.
Sex: men; women	<p>Being diagnosed with cancer is defined as a disability under the Equality Act 2010.</p> <p>A review of the available clinical evidence demonstrates that use of vismodegib resulted in a reduction in the size and number of BCCs, thereby reducing the need for surgery which could in some cases be potentially disfiguring. For this reason, implementation of the policy is considered to have a potential positive impact.</p>	<p>The clinical criteria, based on reliable clinical evidence, in the policy clearly define the eligible patient population to maximise access to treatment.</p> <p>Treatment numbers and access would be monitored through NHS England and NHS Improvement's Prior Approval System.</p>
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	Not applicable.	Not applicable.

4. Main potential positive or adverse impact for people who experience health inequalities summarised

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). Please state **N/A** if your proposition will not impact on patients who experience health inequalities.

Groups who face health inequalities ³	Summary explanation of the main potential positive or adverse impact of your proposition	Main recommendation from your proposition to reduce any key identified adverse impact or to increase the identified positive impact
Looked after children and young people	The policy is specifically for adults and for this reason is not considered to impact this group.	Not applicable.
Carers of patients: unpaid, family members.	<p>The policy may potentially have a positive impact on carers of patients.</p> <p>This is because vismodegib reduces the requirement for potentially disfiguring surgery, which can have a large psychological impact on individual patients, their carers and their families. Furthermore, use of vismodegib may result in patients and their carers having to attend the hospital less frequently and having to take time off work for surgical procedures.</p>	<p>The clinical criteria, based on reliable clinical evidence, in the policy clearly define the eligible patient population to maximise access to treatment.</p> <p>Treatment numbers and access would be monitored through NHS England and NHS Improvement's Prior Approval System.</p>
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	People experiencing homelessness are more likely to suffer from a physical health problem and access to healthcare is known to be a problem for this group (Crisis, 2011). However, this policy is only for people diagnosed with disease	Not applicable.

³ Please note many groups who share protected characteristics have also been identified as facing health inequalities.

Groups who face health inequalities ³	Summary explanation of the main potential positive or adverse impact of your proposition	Main recommendation from your proposition to reduce any key identified adverse impact or to increase the identified positive impact
	and therefore no additional impact on this group is anticipated.	
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	People involved in the criminal justice system would be able to access treatment through prison healthcare services. No specific impact is expected on this group as a result of implementation of the policy.	Not applicable.
People with addictions and/or substance misuse issues	Not applicable.	Not applicable.
People or families on a low income	<p>Cancer treatment is known to have a financial impact on patients with cancer with 4 in 5 people are affected by financial difficulties and incurring, on average, costs of £570 per month (Macmillan Cancer Care, 2017).</p> <p>Vismodegib is an oral medicine that can be taken once daily for planned intermittent schedule. It is thought that use of vismodegib would reduce the requirement for potentially disfiguring surgery. This may result in patients having to attend the hospital less frequently and having to take time off work for surgical procedures. As a result, the policy has the potential to have a</p>	<p>The clinical criteria, based on reliable clinical evidence, in the policy clearly define the eligible patient population to maximise access to treatment.</p> <p>Treatment numbers and access would be monitored through NHS England and NHS Improvement's Prior Approval System.</p>

Groups who face health inequalities ³	Summary explanation of the main potential positive or adverse impact of your proposition	Main recommendation from your proposition to reduce any key identified adverse impact or to increase the identified positive impact
	positive impact on people or families on a low income.	
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	Not applicable.	Not applicable.
People living in deprived areas	<p>There is little information on the incidence of non-melanoma skin cancer for people living in deprived areas in England.</p> <p>However, a review of data in Scotland from 1978–2004, indicates that non-melanoma skin cancer rates are higher in least deprived populations (Doherty et al, 2010). Similarly, data in melanoma skin cancer in the UK indicates that incidence rates are 53% lower for males living in the most deprived areas compared with the least deprived, and 56% lower for females (Cancer Research UK, 2016).</p> <p>For this reason, this policy is not considered to impact on people living in deprived areas.</p>	Not applicable.
People living in remote, rural and island locations	Vismodegib is an oral medicine that can be taken once daily for planned intermittent schedule. It is thought that use of vismodegib would reduce the	The clinical criteria, based on reliable clinical evidence, in the policy clearly define the eligible patient population to maximise access to treatment.

Groups who face health inequalities³	Summary explanation of the main potential positive or adverse impact of your proposition	Main recommendation from your proposition to reduce any key identified adverse impact or to increase the identified positive impact
	requirement for potentially disfiguring surgery. This may result in patients having to attend the hospital less frequently and having to take time off work for surgical procedures. This may positively impact people living in remote, rural and island locations.	Treatment numbers and access would be monitored through NHS England and NHS Improvement's Prior Approval System.
Refugees, asylum seekers or those experiencing modern slavery	Not applicable.	Not applicable.
Other groups experiencing health inequalities (please describe)	Not applicable.	Not applicable.

5. Engagement and consultation

a. Have any key engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

Yes x	No	Do Not Know
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b. If yes, please briefly list up the top 3 most important engagement or consultation activities undertaken, the main findings and when the engagement and consultative activities were undertaken.

Name of engagement and consultative activities undertaken	Summary note of the engagement or consultative activity undertaken	Month/Year
1 Stakeholder testing on the draft policy	The policy proposition was recommended for routine commissioning and underwent stakeholder testing for 2 weeks.	2nd July 2020 to 16th July 2020

		There were eight responses to stakeholder testing, and all respondents fully supported the draft Equality Health Impact Assessment and agreed that the Patient Impact Form represented a true reflection of the patient and carers lived experience of this condition.	
2	PPVAG	The Programme of Care considered that further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.	August 2020

6. What key sources of evidence have informed your impact assessment and are there key gaps in the evidence?

Evidence Type	Key sources of available evidence	Key gaps in evidence
Published evidence	<p>Cancer Research UK, 2016. Available at:- https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/melanoma-skin-cancer/incidence#heading-Six</p> <p>Cancer Research UK, 2018. Available at:- https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/non-melanoma-skin-cancer/risk-factors#heading-One</p> <p>Cancer Research UK, 2020a. Available at:- https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/non-melanoma-skin-cancer/incidence</p> <p>Cancer Research UK, 2020b. Available at:- https://www.cancerresearchuk.org/about-cancer/other-conditions/gorlin-syndrome</p> <p>Crisis, 2011. Available at:- https://www.crisis.org.uk/media/237321/crisis_homelessness_a_silent_killer_2011.pdf https://www.crisis.org.uk/ending-homelessness/homelessness-knowledge-hub/health-and-wellbeing/</p>	

Evidence Type	Key sources of available evidence	Key gaps in evidence
	Doherty et al, 2010. Available at:- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2883152/ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2883152/	
Consultation and involvement findings	The policy proposition underwent stakeholder testing for a period of 2 weeks from 2nd July 2020 to 16th July 2020 and a total of 8 responses we received. The policy was supported by all stakeholders and no specific comments regarding equality and health inequalities were raised.	
Research	Not applicable.	
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	The National Cancer Programme of Care, through its Clinical Reference Group structures and the Policy Working Group for this specific group, has expert knowledge regarding the incidence and treatment of BCC.	

7. **Is your assessment that your proposition will support compliance with the Public Sector Equality Duty?** Please add an x to the relevant box below.

	Tackling discrimination	Advancing equality of opportunity	Fostering good relations
The proposal will support?			.
The proposal may support?		X	
Uncertain whether the proposal will support?	X		X

8. Is your assessment that your proposition will support reducing health inequalities faced by patients? Please add an x to the relevant box below.

	Reducing inequalities in access to health care	Reducing inequalities in health outcomes
The proposition will support?		X
The proposition may support?	X	
Uncertain if the proposition will support?		

9. Outstanding key issues/questions that may require further consultation, research or additional evidence. Please list your top 3 in order of priority or state N/A

Key issue or question to be answered	Type of consultation, research or other evidence that would address the issue and/or answer the question
1 Not applicable.	Not applicable.

10. Summary assessment of this EHIA findings

BCC is the most common form of skin cancer in the UK. People with multiple BCC can have numerous lesions across their body which can result in patients undergoing potentially disfiguring surgery and impacting on an individual's quality of life.

The policy recommends that vismodegib, a targeted, oral cancer medicine, be made available for the treatment of adults with either Gorlin syndrome or non-Gorlin syndrome related multiple BCC who have a minimum of 6 lesions and where surgery could result in significant disfigurement. The policy and clinical criteria defined in the policy are based on the findings of an independent evidence review which demonstrated that use of vismodegib resulted in a reduction in the size and number of BCCs, thereby reducing the need for potentially disfiguring surgery

For this reason, adoption of the policy is considered to improve health outcomes for people with protected characteristics (based on age, disability, race/ethnicity and sex). The policy may also potentially impact groups who face health inequalities

(carers of patients, people or families on a low income and people living in rural, remote or island locations) due to possible reductions in surgeries.

11. Contact details re this EHIA

Team/Unit name:	National Cancer Programme of Care
Division name:	Specialised Commissioning
Directorate name:	Finance, Planning and Performance
Date EHIA agreed:	10 May 2021
Date EHIA published if appropriate:	July 2021